REMARKS

This document is filed in reply to the Office Action dated November 20, 2009 ("Office Action").

Applicants have amended claims 33 and 61-63 to more particularly point out the subject matter they deem as their invention. The amendment to claim 33 has necessitated cancellation of claim 58. Further, Applicants have added new claims 64-77. Support for these amended and new claims is summarized in the table below:

Claims	Support in the Specification
claim 33	original claim 1
claim 61	original claim 3
claims 62-66 and 70-72	page 12, line 17 through page 13, line 17 and tables at pages 14-18
claims 67-69 and 73-75	page 18, lines 10-14
claim 76 and 77	original claim 1, page 13, lines 10-12, and page 18, lines 10-14

In addition, claims 34 and 35 have been amended to promote clarity and claims 38 and 39 cancelled to obviate an indefiniteness rejection. Finally, Applicants have amended the Specification, the table entitled "Fucosyl oligosaccharides" at page 14, to correct two typographical errors. No new matter has been introduced by these amendments.

Upon entry of the amendments, claims 33-37 and 59-77 will be pending and under examination. Applicants respectfully request that the Examiner reconsider this application in view of the following remarks.

Rejection under 35 U.S.C. § 112

Claims 38 and 39 are rejected for indefiniteness. See the Office Action, page 2, lines 12-14. Applicants have cancelled these two claims.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejects claims 33-39, 58, and 59 for anticipation by Prieto et al., US 2002/0019991 ("Prieto"), Yanmaele et al., US Patent 6,291,435 ("Yanmaele"), or Yolken et al., J. Clin. Invest., 1992, ("Yolken") in view of Wilson et al., J. Proteome Res., 2008 ("Wilson"). See the Office Action, page 3, lines 17-18, page 4, lines 5-6, and

lines 10-12. As claims 38, 39, and 58 have been cancelled, Applicants address below only claims 33-37 and 59.

Independent claim 33 will be discussed first. This claim, as amended, covers a method for treating or reducing the risk of infection using a molecule including a **fucose group in an α1,3 linkage or an α1,4 linkage to a galactose group**.

As pointed out by the Examiner, Prieto discloses "administration of a composition comprising a **fucose** in an **α1,2 linkage** for the prevention or treatment of enteric infections, *V. cholerea*, or *E. coli*." See the Office Action, page 3, lines 19-21. This reference discloses a number of fucose-containing oligosaccharides, e.g., 2'fucosyl-lactose, difucosyllactose, and Fucα1-2Galβ1-4[Fucα1-3]Glc, none of which includes a **fucose group in an α1,3 or α1,4 linkage to a galactose group**. See page 3, paragraph [0030]. Clearly, Prieto does not disclose the molecule recited in amended claim 33, i.e., a molecule including **a fucose group in α1,3 or α1,4 linkage with a galactose group**.

Yanmaele discloses various oligosaccharides for use in treating enteropathogenic *E. coli* (EPEC) infection. See the Abstract and Tables 1 and 2. All of the disclosed oligosaccharides DO NOT include **a fucose group in an α1,3 linkage or an α1,4 linkage to a galactose group,** a feature of the molecule recited in amended claim 33. Thus, this reference also does not teach the molecule required by this claim.

Yolken discloses that human milk mucin inhibits rotavirus replication. See the Title. As evidenced in Wilson, human milk fat globule membrane mucin includes sugar moieties Lewis a and Lewis b, having the structures of Galβ1-3(Fucα1-4)GlcNAcβ1- and Fucα1-2Galβ1-3(Fucα1-4)GlcNAcβ1-, respectively. In these two sugar moieties, fucose is either in an α1,2 linkage with galactose or in an α1,4 linkage with GlcNAc, but NOT in an **α1,3 or α1,4 linkage with a galactose group**, as required by claim 33. Neither Yolken nor Wilson teaches that human milk mucin contains a sugar moiety that includes fucose and galactose in one of the two linkages recited in this claim.

For the reasons set forth above, amended claim 33 is not anticipated by Prieto, Yanmaele, or Yolken as evidenced by Wilson. Nor are claims 34-37 and 59, all of which depend from claim 33, directly or indirectly.

The Examiner further rejects claims 61-63 for anticipation by Yolken in view of Wilson.

Among the rejected claims, claim 61 ultimately depends from claim 33. Thus, for reasons set forth at page 11, supra, this claim is novel over Yolken in view of Wilson.

Turning to claims 62 and 63, Applicants point out that these two claims, as amended, are each directed to a method for treating or reducing the risk of infection with a molecule having at least two sugar moieties, one being either **2'FL** (i.e., Fucα1-2Galβ1-4Glc) or **2'FLNAc** (i.e., Fucα1-2Galβ1-4GlcNAc) and the other being one of the particular sugar moieties recited in amended claim 62.

As discussed above, Yolken discloses use of human milk mucin for treating rotavirus infection and, according to Wilson, this glycoprotein contains sugar moieties **Lewis a** and **Lewis b**. Neither reference teaches that human milk mucin includes the sugar moiety combination required by both amended claims 62 and 63, i.e., a combination containing at least **2'FL** or **2'FLNAc** and another specified oligosaccharide. Thus, these two claims are novel over Yolken in view of Wilson.

In view of the above remarks, Applicants respectfully request that the Examiner withdraw this rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 33-39, 58-60, 62, and 63 are rejected for obviousness on at least one of two grounds. As claims 38, 39, and 58 have been cancelled, Applicants address below these two grounds as applied to claims 33-37, 59, 60, 62, and 63, the only claims remaining at issue.

I

Claims 33-35, 37, 59, and 60 are rejected for obviousness over Yanmaele in view of Stahl et al., US Patent 5,470,843 ("Stahl") and Prestwich et al., J. Controlled Release, 1998 ("Prestwich"). See the Office Action, page 6, lines 6-8.

As discussed above, amended claim 33 is directed to a method of treating or reducing the risk of infection using a molecule that includes **a fucose group in an α1,3 linkage or an α1,4 linkage to a galactose group.**

As also discussed above, Yanmaele does not mention any oligosacchairde that includes a fucose group and a galactose group in one of the two linkages required by amended claim 33, let alone a molecule containing such an oligosaccharide for treating infection.

Stahl, according to the Examiner, discloses "various glycosaminoglycans, including hyaluronic acid, hav[ing] utility as a support for multivalent oligosaccharide products to be administered for the treatment of bacterial and viral disorder." See the Office Action, page 6, third paragraph. This reference lists numerous anti-bacterial/viral oligosaccharides (see column 8, line 36 through column 10, line 64), none of which contains a fucose group in an α1,3 linkage or an α1,4 linkage to a galactose group, as recited in amended claim 33. In other words, this reference also does not suggest use of any oligosaccharide containing fucose and galactose in one of the two just-mentioned linkages for treating bacterial/viral infection.

Prestwich does not cure the deficiency of both Yanmaele and Stahl. This reference, merely disclosing chemical modification of hyaluronic acid (see the Title), is irrelevant to use of sugar-containing molecules for treating infection.

In view of the foregoing reasons, Applicants respectfully submit that Yanmaele, Stahl, and Prestwich, either taken alone or in combination, do not render amended claim 33 obvious. Nor do they render obvious claims 34, 35, 37, 59, and 60, all of which depend from claim 33.

II

Claims 33-37, 59, 62, and 63 are rejected for obviousness over Prieto. See the Office Action, page 7, lines 1-2.

As pointed out above, Prieto discloses use of an oligosaccharide containing a **fucose in an α1,2 linkage** for treating infection and, differently, amended claim 33 requires a molecule containing **a fucose group in an α1,3 linkage or an α1,4 linkage to**

a galactose group. This reference does not mention any molecule containing a sugar moiety that includes a fucose and a galactose in one of the two linkages recited in amended claim 33. Nor does this reference suggest that such a molecule could be used for treating infection. Clearly, it does not render obvious amended claim 33, as well as claims 34-37 and 59, all dependent from this claim.

Applicants now turn to claims 62 and 63, the other two rejected claims. As discussed above, amended claims 62 and 63 each cover a method for treating or reducing the risk of infection using a molecule having at least two sugar moieties, one being either 2'FL or 2'FLNAc and the other being one of the specific oligosaccharides recited in amended claim 62.

As acknowledged by the Examiner, Prieto "does not particularly disclose a composition or conjugate having more than one oligosaccharide." See the Office Action, page 7, fourth paragraph. On the other hand, based on a disclosure in Prieto, paragraph [0030], i.e., "... include at least one fucose residue in an α1,2 linkage ...," the Examiner concludes that it would have been obvious to use a molecule containing at least two sugar moieties for treating infection. See the Office Action, page 7, fourth and fifth paragraphs. Applicants respectfully disagree and would like to point out that the Examiner has misread paragraph [0030] in Prieto, which states:

> "Compositions which include at least one fucose residue in an α1,2 linkage include, for example, 2'-fucosyl-lactose (Fucα1-2Galβ1-4Glc), **difucosyl**lactose, **Fuc**α1-2Galβ1-4[**Fuc**α1-3]Glc, glycoproteins or glycopeptides containing the structure Fucα1-2Galβ1-4Glcβ1-3 ..."

All of the examples disclosed in this paragraph include at least one fucose residue that is in an α1,2 linkage with another sugar group. Some of them include two fucose residues (see highlighted), at least one of which is in an α1,2 linkage. In view of these examples, a skilled person in the art would have readily known that the phrase "include at least one fucose residue in an α1,2 linkage" used in paragraph [0030] describes a particular family of oligosaccharides, each member having one or more fucose residues; it does not relate to any molecule containing two or more oligosaccharide moieties.

Thus, contrary to the Examiner's belief, paragraph [0030], particularly the phrase quoted above, does not suggest any molecule containing two more oligosaccharide moieties, as required by amended claims 62 and 63.

For the above reasons, Applicants submit that Prieto does not suggest the molecule required by amended claims 62 and 63, i.e., including at least two oligosaccharide moieties, one being 2'FL or 2'FLNAc. Therefore, these two claims are not obvious over Prieto.

New claims

New claims 64-69 depend from claim 62. For the same reasons set forth *supra* at page 12, 1st to 5th paragraphs, and pages 13-14, section II, these claims are neither anticipated nor rendered obvious by any of Prieto, Yanmaele, Yolken, Wilson, Stahl, and Prestwich.

Further, new claims 70-75 are each drawn to a method for treating or reducing the risk of infection using a pharmaceutical composition containing at least two oligosaccharides, one of which is 2'FL or 2'FLNAc and the other is one of the particular oligosaccharides listed in claim 70. None of the six cited references teaches or suggests the particular two-oligosaccharide combination required by claims 70-75. Thus, they do not anticipate or render obvious these claims.

Finally, new claims 76 and 77 cover a method for treating infections caused by Campylobacter, Shigella, Listeria, HIV, Noroviruses, *V. cholerea*, *Candida albicans*, or *Helicobacter pylori* with a molecule containing a particular sugar moiety that includes a fucose group in an α1,3 linkage or an α1,4 linkage to a galactose group, a fucose group in an α1,4 linkage to an *N*-acetylglucosamine group, or a fucose group in an α 1,3 linkage to an *N*-acetylglucosamine group. None of the cited references teaches or suggests use of a molecule containing one of the recited sugar moieties for treating one of the infections targeted by the claimed method. Thus, these two new claims are also novel and non-obvious over the cited references.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

No fee is believed due at this time. Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 50051-002US1.

Respectfully submitted,

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Y. Jenny Chen, Ph.D., J.D.
Reg. No. 55,055

Customer No. 69713
Occhiuti Rohlicek & Tsao LLP
10 Fawcett Street
Cambridge, MA 02138
Telephone: (617) 500-2511
Facsimile: (617) 500-2499
126429.doc